



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,674	10/25/2001	Robert C. Ladner	DYAX/002CIP2	2458
1473	7590	07/14/2005	EXAMINER	
FISH & NEAVE IP GROUP ROPES & GRAY LLP 1251 AVENUE OF THE AMERICAS FL C3 NEW YORK, NY 10020-1105			EPPERSON, JON D	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/045,674	LADNER ET AL.	
	Examiner	Art Unit	
	Jon D. Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 26 April 2005.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-116 is/are pending in the application.
 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 14-16, 19, 39-53, 63 and 115 is/are rejected.
 7) Claim(s) 14, 19-32, 39-53, 63 and 115 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 25 October 2001 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. <u>4/19/05</u>
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>8/29/03; 4/4/02</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1-13, 17, 18, 19-32 (in part), 33-38, 39-53 (in part), 54-62, 64-114 and 116.

DETAILED ACTION

Status of the Application

1. Receipt is acknowledged of a Response to a Restriction Requirement, which was dated on April 26, 2005.

Status of the Claims

- 2.. Claims 1-116 were pending in the present application.
3. Applicant's response to the Restriction and/or Election of Species requirements is acknowledged (Applicant elected with traverse Group IV, i.e., claims 14-16, 19-32 (in part), 39-53 (in part), 63 and 115) and claims 1-13, 17, 18, 19-32 (in part), 33-38, 39-53 (in part), 54-62, 64-114 and 116 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim (see ***Response to Restriction and/or Election of Species*** below).
4. Please note: Applicant's elected species (Subgroup 3: Species of what nucleic acid encodes = heavy chain, human FR1; Subgroup 4: Species of autoimmune disease = systemic lupus erythematosus; Subgroup 5: Species of isolated cells = Blood cells) were found in the art. The Examiner refers Applicants to MPEP § 803.02 for species election practice (emphasis added):

Art Unit: 1639

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. *The prior art search, however, will not be extended unnecessarily to cover all nonelected species.* Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

5. Therefore, claims 14-16, 19-32 (in part), 39-53 (in part), 63 and 115 are examined on the merits in this action.

Response to Restriction and/or Election of Species

6. Applicant's election of Group IV (i.e., claims 14-16, 19-32 (in part), 39-53 (in part), 63 and 115) **with traverse** is acknowledged.
7. The traversal is on the ground(s), "Applicants ... traverse the restriction requirement to the extent it does not include claims 64-72 (in part) and 106, 107 and 116 (in part) ... Like other of the claims in Group IV, claims 64-72, 106, 107 and 116 recite a library of a collection of members of a diverse family of peptides" and Applicants further note that they have "... amended claims 19, 20, 21, 30, 33, 39, 43, 45, 47, 50, 61, 64, 107, 113 and 116 to direct them solely to the subject matter of Group IV or to the methods of producing that subject matter" (e.g., see 4/26/05 Response, pages 37-38, section 1).

Art Unit: 1639

8. These arguments were fully considered but were not found persuasive. Applicants amended claim 64 (and thus dependent claims 65-72) to depend on claims 60, 61 and 62 (i.e., Groups II and III). As stated in 2/28/05 Restriction Requirement, the inventions of Groups II/III and IV are drawn to patentably distinct methods and/or product (i.e., e.g., which are directed to different purposes, use different materials, recite different method or process steps for the preparation of different product(s), screening of different characteristics, such as different binding affinities, different biochemical reaction conditions, etc. or lead to different final results). Specifically, Groups III and IV represent separate and patentably distinct products because Group III requires a "genetic package" that is not required by Group IV (i.e., which is drawn to a library of proteins). Thus, a search for Groups III and IV would not be coextensive. For example, a library of proteins can be found in synthetic organic chemistry journals the produce said library via solid-phase synthesis (e.g., Journal of Organic Chemistry), which would not include the use of genetic packages. Thus an undue search burden exists. Furthermore, it was previously stated that if Groups II and IV are to be construed as process of making and product made, the inventions can be shown to be distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different products or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, (2) the product as claimed can be made by another materially different process (e.g., the oligonucleotide synthesis without restriction enzymes). In addition, (1) the process of Group II could be used to make affinity protein column purification systems and/or homing devices for drug delivery. Furthermore, the products of Group IV can be made using other materially different processes (e.g., the proteins and/or immunoglobulins can be

made with ribosome display and the genetic packages can be made without the use of restriction enzymes). Thus, these inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and products would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

9. With regard to claims 106, 107 and 116 (i.e., Group II), as stated in 2/28/05 Restriction Requirement, if Groups II and IV are to be construed as drawn process of making and product made, then the inventions can be shown to be distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different products or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). Here, (2) the product as claimed can be made by another materially different process (e.g., the oligonucleotide synthesis without restriction enzymes). In addition, (1) the process of Group II could be used to make affinity protein column purification systems and/or homing devices for drug delivery. Furthermore, the products of Group IV can be made using other materially different processes (e.g., the proteins and/or immunoglobulins can be made with ribosome display and the genetic packages can be made without the use of restriction enzymes). Thus, these inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and products would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an

undue search burden, and restriction for examination purposes as indicated is proper. Please note that claims 106 and 107 have been interpreted as "method" claims because they further limit claim 104, which is drawn to a "method for preparing" a library.

10. Applicant's election of species with traverse is also acknowledged.
11. The election of species traversal is on the ground(s) that "... many of the species groups ... were unlikely to make the search easier [i.e., no burden]" (see 4/26/05 Response, page 38, section 2).
12. These arguments were fully considered but were not found persuasive (in part). As stated previously in the 2/28/04 Restriction requirement, the different species (e.g., for Subgroups 3-5) would require different searches and there is no expectation that the searches would be coextensive. For example, the species of autoimmune disease are drawn to different etiologies and would be searched in different medical and/or research journals. Likewise, the species of library that is produced consist of proteins with different structure that could be separately classified and/or search in separate journals. Thus, the Examiner maintains that this does create an undue search burden for Subgroups 3-5. For Subgroups 1, 2 and 6-10 the Examiner finds Applicants' arguments persuasive and hereby withdraws the species election.
13. As a result, the restriction requirement and/or election of species is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

14. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98 (b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on the form PTO-892, they have not been considered.
15. The references listed on applicant's PTO-1449 forms have been considered by the Examiner (e.g., 8/29/03; 4/4/02). A copy of each form is attached to this Office Action.

Specification

16. The abstract of the disclosure is objected to because it does not include the technical disclosure of the improvement (e.g., the use of class II-s restriction enzymes to make the library). In addition, the abstract fails to recite the method steps of the process (e.g., see paragraph 17, section (5)) and also inappropriately recites the "purported merits" or "speculative applications" (see paragraph 17). Correction is required. See MPEP § 608.01(b).
17. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, ***the abstract should include the technical***

Art Unit: 1639

disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should **not refer to purported merits or speculative applications** of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) **if a process, the steps.**

Extensive mechanical and design details of apparatus should not be given.

18. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). Here, Applicants' specification provides the wrong priority documents in the first paragraph of the specification (e.g., "06/198,069" and "XX/XXX,XXX"). The appropriate correction is requested.

Objections to the Claims

19. Claims 19-32, 39-53, 63 and 115 are objected to because of the following informalities:

A. Claims 20, 30-32 are objected to under 37 CFR 1.75(c) as being improper form because they do not refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, claims 20, 30-32 have not been further treated on the merits.

Art Unit: 1639

B. Claims 21-29 are objected to under 37 CFR 1.75(c) as being improper form because a multiple dependent claim depends from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, claims 21-29 have not been further treated on the merits.

C. Claims 14, 19, 39-53, 63 and 115 are objected to as containing non-elected subject matter. Here, Applicants elected Group IV (i.e., a library). However, claim 14, 19, 39-53, 63 and 115 are also drawn to and/or otherwise depend from non-elected methods. The Examiner notes that this objection will be withdrawn in the event that the method claims are properly rejoined with the product claim in accordance with *In re Ochiai*. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996).

D. Claims 19 and 39-52 contain the claim language “The methods or libraries according to any one of claims ...” in lines 1-2, which mistakenly uses the plural form of “method” and “library” instead of the grammatically correct singular form. Correction is requested.

Claims Rejections - 35 U.S.C. 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

20. Claim 19, 39-53 are rejected under 35 U.S.C. 101 because the claim is directed more than one statutory class of inventions i.e., “methods or libraries” (e.g., see the preamble of claims 19 and 39-53). Thus, claims 19 and 39-53 are drawn to two statutory classes of invention (i.e., a

Art Unit: 1639

method of making and a product), rather than a single statutory class of invention. This is not permissible. For example, see MPEP § 2173.05(p), "Such claims should ... be rejected under 35 U.S.C. 101 based on the theory that the claim ... embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only" (emphasis added).

The Examiner concedes that there are situations where claims are permissively drafted to include a reference to more than one statutory class of invention (e.g., see MPEP § 2173.05(p) disclosing "product-by-process" claims), but the Examiner notes that those situations are only permissible because Applicants make clear that the "product" and NOT the "process" is being claimed (e.g., see MPEP § 2173.05(p), "A claim to a device, apparatus, manufacture, or composition of matter may contain a reference to the process in which it is intended to be used without being objectionable under 35 U.S.C. 112, second paragraph, so long as it is clear that the claim is directed to the product and not the process") (emphasis added). Here, it would appear that both the method of making and the product are being claimed in the alternative by Applicants' use of the "methods or libraries" language.

Claims Rejections - 35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

21. Claims 14-16, 19, 39-53, 63 and 115 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1639

A. For claims 14-16, 63 and 115, the recites the limitation “the diversity of the family” in line three of each claim. There is insufficient antecedent basis for this limitation in the claim. Furthermore, it is not clear how a library that “comprises a collection of members of a diverse family of peptides, polypeptide or proteins” could simultaneously comprise a “portion of the diversity of the family” because said library already comprises the “entire” diversity (i.e., the library can not simultaneously be composed of “all” and also some smaller “portion” of members). For example, if the library were drawn to just a “portion” of the members then it necessarily wouldn’t contain “all” the members. Applicants’ are requested to clarify and/or correct. Therefore, claim 14-16, 63, 115 and all dependent claims are rejected under 35 USC 112, second paragraph.

B. *Claim 14* is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: When claim 14 depends alternatively from claims 7 and 8, no “expression” steps are recited that would produce the claimed library of peptides, polypeptides or proteins (e.g., compare to claims 9 and 10; step (iv)). Therefore, claim 14 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

C. *Claims 15-16* are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: An “expression” step for producing

the claimed diverse family of peptides, polypeptides or proteins. Therefore, claims 15-16 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

D. ***Claim 115*** is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: When claim 115 depends alternatively from claims 101 and 102, no “expression” and/or “displaying” steps are recited that would produce the claimed library of peptides, polypeptides or proteins (e.g., compare to claims 9 and 10, step (iv)). Therefore, claim 115 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

E. ***Claims 19 and 39-53*** are indefinite because Applicants are claiming more than one statutory class of invention (i.e., “methods or libraries”). This is not permissible. For example, see *In Ex parte Lyell* wherein the Court struck down a claim drawn to two statutory classes of invention, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990) (a claim directed to an automatic transmission workstand and the method steps of using it was held to be ambiguous and properly rejected under 35 U.S.C. 112, second paragraph). See more generally MPEP § 2173.05(p). Please note that other “statutory hybrid” claims are not rejected like “product-by process” claims because Applicants make clear what is being claimed i.e., the product (see MPEP § 2173.05(p), “A claim to a device, apparatus, manufacture, or composition of matter may contain a reference to the process in which it is intended to be used without being objectionable under 35 U.S.C. 112, second paragraph, so long as it is clear that the claim is directed to the product and not the process”) (emphasis added). That is not the case here. Applicants use the alternative

Art Unit: 1639

expression of “methods or libraries” in the preamble of claims 19 and 39-53, which reads on more than one statutory class of invention.

F. **Claim 15** recites the limitation “the region in which cleavage is desired” in line 9. There is insufficient antecedent basis for this limitation in the claim. Therefore, claim 15 and all dependent claims are rejected under 35 USC 112, second paragraph. The Examiner recommends “a region in which cleavage is desired.”

G. **Claims 48 and 50**, recite the limitation “the partially double-stranded oligonucleotide” in lines 2-3. There is insufficient antecedent basis for this limitation in the claim when the claim depends on claims 14 (which subsequently depend on claims 7 and 9, which do not recite this limitation) and 15. Therefore, claim 48, 50 and all dependent claims are rejected under 35 USC 112, second paragraph.

Claims Rejections – 35 U.S.C. 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1639

22. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

23. Claims 14-16, 19, 39-53, 63 and 115 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Burton et al. (WO 94/07922) (Date of Patent is April 14, 1994).

For *claims 14-16, 19, 39-53, 63 and 115*, Burton et al. disclose a library comprising a collection of genetic packages that display a member of a diverse family of peptides, polypeptides or proteins and collectively display at least a portion of the diversity of the family (e.g., see page 3, Combinatorial Phagemid Libraries Section; see also page 4, lines 6-15, wherein combinatorial libraries of human anti-HIV antibodies are disclosed, "Methods have now been discovered using the phagemid vectors to identify and isolate from combinatorial libraries human monoclonal antibodies that neutralize HIV, and allow the rapid preparation of large numbers of neutralizing antibodies of completely human derivation"; see also figures 5 and 15; see also page 41, section F, especially page 42, lines 18-30, "In one embodiment, the method involves preparing a phagemid library of human monoclonal antibodies by using donor immune cell

messenger RNA from HIV infected donors ... Alternatively, the library can be synthetic, or can be derived from a donor who has an immune response to other antigens"; see also page 43, lines 19-23; see also page 44, lines 9-13, see also figures 6-13; see also figure 10; see also page 18, lines 3-4; see also page 42, lines 18-30; see also page 44, lines 9-13). Although Burton et al. do not disclose that their libraries are formed by the same method steps as recited in claims 7-10, 60, 61, 101, 102, 104 or 113, the products of Burton et al. appear to be the same as those recited by the instant claims, regardless of their method of manufacture (e.g., see MPEP 2113). That is, both methods produce a library of a diverse family of peptides, polypeptides or proteins that collectively display at least a portion of the diversity of the family.

The libraries of Burton et al. meet all of the limitations of the claimed library (see above) except for the product-by-process limitations and thus would either anticipate or render obvious the claimed library because the process of Burton et al. produce the same or a substantially similar product (see above). See MPEP § 2113, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.' *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)." Here, Applicants claims are drawn to a "library" (i.e., a product), but are defined by various method steps that produce said library (e.g., see claim 14, "A library [i.e., a product] ... being produced using the methods of claims 7, 8,

Art Unit: 1639

9 or 10 [i.e., a process]) and, as a result, represent "product-by-process" claims. One of ordinary skill would expect the library of a diverse family of peptides, polypeptides or proteins to be the same no matter how it was synthesized. When the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either 35 U.S.C. 102 or 35 U.S.C. 103 is eminently fair and acceptable. PTO is not equipped to make and then compare products. *In re Brown*, 459 F.2d 531, 173 USPQ 685 (CCPA 1972).

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
July 7, 2005

